UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

In Re: Recalled Abbott Infant Formula Products Liability Litigation THIS DOCUMENT RELATES TO: ALL CASES	Case No. 22 C 4148 MDL No. 3037 Hon. Judge Matthew F. Kennelly
CHARLOTTE WILLOUGHBY, LAKENDREA CAMILLE MCNEALY, SHAYLYNN DOXIE, BRITTNEY GRAY, KATLEENA HELMICK, LANI HOLIDAY, ASHLEY POPA, and DENIEGE REVORD individually and on behalf of a class of similarly situated individuals, Plaintiffs, v. ABBOTT LABORATORIES, Defendant.	Case No. 22 C 1322 Hon. Judge Matthew F. Kennelly
In Re: Recalled Abbott Infant Formula Products Liability Litigation	Case No. 23 C 338 Hon. Judge Matthew F. Kennelly

JOINT STATUS REPORT
FOR THE AUGUST 11, 2023 CASE MANAGEMENT CONFERENCE

Per the Court's Order, ECF 151 (Case No. 1:22-cv-4148), the parties provide the following joint status report in advance of the Case Management Conference scheduled for August 11, 2023. The parties have separated this report into two primary sections: one addressing the MDL (Case No. 1:22-cv-4148) and one addressing the *Willoughby* consolidated action (Case No.

1:22-cv-1322). Each section is submitted on behalf of the parties and counsel involved in the respective actions.

REPORT ON MDL MATTERS

I. STATUS OF FILED MDL CASES

The parties are presently aware of 62 personal injury cases pending in the Northern District of Illinois pertaining to Abbott's recalled infant formula.

The 16 class action complaints alleging economic loss were dismissed pursuant to Case Management Order No. 11 (*see* ECF 139 (Case No. 1:22-cv-4148)). The Clerk has entered judgment in each of the underlying actions since the last status conference with the Court on June 27, 2023.

The parties believe all related cases have been associated with the MDL with the exception of the following, which the parties request be so associated:

- 1:23-cv-04074 *Butler v. Abbott Laboratories Inc.*
- 1:23-cv-04220 *Houser v. Abbott Laboratories, Inc.*
- 1:23-cv-05130 *Highsmith v. Abbott Laboratories*

II. JOINT PROPOSAL ON BELLWETHER SELECTION PROCESS AND SCHEDULE

Per the Court's June 27, 2023 Order directing the parties to submit a proposal regarding bellwether selection, ECF 151, Abbott and leadership of the Plaintiffs' Steering Committee ("PSC") jointly submitted a proposed Case Management Order on July 24, 2023 that would govern a bellwether process for the personal injury complaints in this MDL, ECF 159 & 159-1. The parties will be prepared to discuss the Proposed Order at the upcoming status conference.

III. STATUS OF MDL DISCOVERY

A. General Status

General discovery remains ongoing. The parties have continued to meet and confer over the PSC's October 21, 2022 discovery requests. Since the parties' June 16, 2023 status report, Abbott has produced an additional 49,735 documents and 148,610 pages, bringing its total production to nearly 127,000 documents and 400,000 pages drawn from Abbott's application of the parties' negotiated search terms and from Abbott's central repositories. As productions continue, Abbott and the PSC have been engaged in regular meet and confers across several matters including a defense fact sheet or equivalent mechanism as well as additional custodians and electronic database disclosures.

The parties remain committed to meeting and conferring on discovery issues in which there remains disagreement. The PSC provided a detailed letter on June 14, 2023 to Abbott involving areas of disagreement applicable to the PSC's first set of discovery requests. Since the last report to the Court, the parties met and conferred on June 20, July 13, July 17, and July 26 to discuss and further clarify the issues raised in the PSC's June 14 letter, as well as other issues relating to discovery. Following these discussions, Abbott is in the process of preparing a written response (at the PSC's request), which it expects to provide shortly; as a result, there may be further areas of dispute for the Court as the Parties conclude their meet-and-confer attempts on these issues. On June 14, 2023, the PSC served a second set of requests for production on Abbott, which Abbott will respond to on August 14 per agreement by the parties.

For their part, individual Plaintiffs have produced certain documents and records pursuant to the Plaintiff Fact Sheet process. *See* ECF 32.

B. Current Areas of Impasse

The parties remain engaged in productive discussions relating to a variety of discovery-related issues and, as set forth above, participate in regular meet-and-confer teleconferences. At present, however, the parties have reached impasse on two issues: (1) the appropriate presumptive[1] date on which Abbott's custodial and non-custodial document searches should begin in response to Plaintiffs' 111 document requests; and (2) the relevance of documents concerning the production of powdered infant formula at Abbott's separate manufacturing facility in Casa Grande, Arizona. Subject to the Court's preference otherwise, the parties request the Court order simultaneous briefing on these three issues not to exceed 12 pages total to be filed by August 22, 2023. To help the Court decide on parameters for briefing, the parties have agreed to provide a "preview" of their respective position on these issues.

i. Presumptive Date Range

PLAINTIFF'S POSITION:

Plaintiffs served written discovery in these cases and in the discovery, defined the relevant time period of 2018 to present. While Abbott has taken the position that it need only apply the parties' agreed-upon search terms to documents within custodial files that are dated no earlier than Jan. 1, 2020, the PSC maintains that the presumptive date range should begin on Jan. 1, 2018.

As Abbott acknowledges, a plaintiff (*San Miguel*) whose case is before this Court was diagnosed with *Cronobacter* in 2019. The *San Miguel* family alleges catastrophic, life-changing

[1] In the PSC's view, the term "presumptive" relates to the establishment of a default date range applicable to document productions responsive to the PSC's Requests for Production. As stated in the PSC's first Requests for Production:

> Unless otherwise stated in a particular request for production, the relevant time period of these requests is the period of 2018 through the present (i.e., a continuing time period not limited to the date You respond to these Requests for Production), and shall include all Documents which relate or refer to this period even though prepared before the relevant time period.

injuries sustained by their infant upon being fed Abbott PIF produced in Sturgis. Their liability allegations involve the same quality failures and misconduct within the same factory as every other plaintiff with a case filed in this MDL. Adopting Abbott's position would unreasonably deny the *San Miguel* family the same type of evidence provided to every other family whose infant was alleged to have been injured by contaminated Abbott PIF, only later in time.

Abbott's Sturgis plant is no stranger to contamination. In 2010, the FDA called Abbott out for its failure to maintain "conditions and controls" at Sturgis needed to limit contamination[2]:

> **OBSERVATION 1**
>
> Failure to manufacture foods under conditions and controls necessary to minimize contamination.

As reported in a September 2018 FDA Establishment Inspection Report, from an inspection conducted in September 2018, Abbott prepared two non-conformance reports for two instances of confirmed *Cronobacter* results and received at least two complaints involving *Cronobacter* infections.[3] In a September 2019 Form 483, the FDA called out Abbott's Sturgis plant for inadequate testing of powdered infant formula (PIF) to ensure it met "required microbiological quality standards."[4]

> DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:
>
> **OBSERVATION 1**
>
> You did not test a representative sample of a production aggregate of a powdered infant formula at the final product stage and before distribution to ensure that the production aggregate meets the required microbiological quality standards.

[2] FDA, Form FDA 483 (issued on Oct. 22, 2010), available at https://www.fda.gov/media/79030/download (last visited on Aug. 2, 2023). While this citation relates to the appearance of beetles in infant formula, it does not take a vast leap to associate Abbott's failure to prevent visible pest contamination with a failure to prevent microscopic pest contamination.

[3] FDA, September 28, 2018 Establishment Inspection Report, available at https://www.fda.gov/media/159323/download (last visited January 31, 2023).

[4] FDA, Form FDA 483 (issued on Sept. 24, 2019); https://www.fda.gov/media/157319/download (last visited October 2, 2022).

Agency inspections are merely a snapshot in time subject to limitations in resources and a manufacturer's candor. As contained in the Abbott whistleblower's report[5]:

> ***The 2019 FDA Audit*** – Active efforts were undertaken and even celebrated during and after the 2019 FDA audit to keep the auditors from learning of certain events believed to be associated with the discovery of micros in infant formula at the Sturgis site.

The Agency issued a Form 483 every subsequent year in which it conducted an inspection of the Sturgis facility leading to the recall and in each instance cited growing concerns about microbiological contamination. The FDA Deputy Commissioner in place during the 2022 Recall provided Congress sworn testimony laying out numerous fundamental flaws with the Sturgis facility and its management, including "lack of environmental control," "old spray dryer with large cracks," "known product contamination," "lax standards," leading him to conclude:

> Lastly, and in summary, the factors presented above supported a conclusion that PIF made at Abbott's Sturgis plant was produced under insanitary conditions and a likely source of ongoing, sporadic contamination of PIF with multiple strains *C. sakazakii* **over time**, notwithstanding a lack of a match by WGS between the plant's environment and/or finished product and two clinical isolates.[6]

(emphasis added). These problems grew worse with time until the FDA forced Sturgis' closure, which was followed by industry-wide reforms including improved Agency oversight.[7]

Finally, it bares emphasis that the parties' search terms are necessarily self-limiting. If as Abbott suggests that prior to 2020, there existed no conditions in Sturgis conducive to microbial contamination of PIF, then the search terms would not return any responsive documents. Indeed, counsel for Abbott has indicated that it collected custodial documents going back to 2018 already

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[5] Available at https://int.nyt.com/data/documenttools/confidential-disclosure-re-abbott-laboratories-10-19-2021-redacted-1/b9ec16287b0384d3/full.pdf (last accessed Aug. 4, 2023).

[6] Available at https://oversight.house.gov/wp-content/uploads/2023/03/Yiannas-Testimony_-House-Subcomm_March-27-2023.pdf (last accessed Aug. 4, 2023).

[7] Available at https://www.fda.gov/food/infant-formula-guidance-documents-regulatory-information/status-update-fdas-infant-formula-response-activities (last accessed Aug. 4, 2023).

so any argument as to burden is limited when the documents are already in place. Thus, PSC reiterates that a presumptive date range beginning on January 1, 2018 is necessarily reasonable.

ABBOTT'S POSITION:

Notwithstanding Plaintiffs' mischaracterization of the relevant history of the Sturgis facility—which Abbott will address at the appropriate time—a January 1, 2020 start date for Abbott's custodial and non-custodial searches is appropriately calculated and proportional to lead to the production of evidence relevant to the personal injury complaints still at issue.

First, the original rationale for Plaintiffs' position that discovery should extend back to January 1, 2018 was that—at the time—certain MDL Plaintiffs possessed economic loss claims, with putative classes beginning in April 1, 2023. However, the Court dismissed those claims on May 22, 2023. *See* ECF 139. In the absence of those claims, Plaintiffs have pivoted to attempt to justify their January 1, 2018 proposal, which is overbroad for the reasons described herein.

Second, a January 1, 2020 start date would afford Plaintiffs ample discovery from before manufacture of the recalled batches of infant formula that led to the filing of cases centralized in this MDL. Those batches were manufactured in or after ***October 2020***, meaning Abbott's proposed start date would provide an nine months of extra context surrounding the policies and practices in place at Abbott's Sturgis facility, long before any recalled batch was manufactured.

Third, not only were all recalled batches manufactured in October 2020 or later, no batch of formula specifically identified by Plaintiffs as the alleged cause of their injuries (in the Plaintiff Fact Sheet process) was manufactured earlier than ***November 2020***. Abbott has already produced all batch records associated with these products—more than thirty batches to date—and has agreed to search custodial files of agreed-upon custodians, using agreed-upon search terms, from 11 months prior to the manufacture date of the earliest at-issue batch of product identified by

Plaintiffs, which is more than sufficient to capture documents and communications relevant to all Plaintiff-identified batches.

Fourth, the alleged dates of injury for the cases that remain in this MDL are concentrated between 2021 and 2022. Out of 61 cases filed at present, all but one (98.4%) allege a date of injury in or after 2021. A ***single*** case alleges injury in late 2019, but the Plaintiffs in that case do not identify a batch number associated with the consumed product. A single, anomalous case hardly warrants extending discovery nearly three years earlier than all other cases in the MDL, particularly since this lone case from a unique time period cannot be representative of any other case in the MDL.

Fifth, requiring Abbott to search files earlier than January 1, 2020 would not only be unlikely to lead to the production of probative evidence, it would impose a substantial burden on Abbott. Abbott has already agreed to sweeping, broad search terms that, when applied to the files of the 29 custodians agreed upon to date would yield nearly 300,000 email files alone dating back to Abbott's proposed January 1, 2020 date (not including mobile and other instant messages or other electronic files from databases or on custodians' hard drives). Putting aside databases, mobile data, and other instant messages, extending the start date back to January 2018 would require Abbott to search an additional 80,000 email files alone—an increase of 27% for those custodians. Many of the databases responsive to Plaintiffs' requests, including the consumer complaints and the quality reports databases, require non-attorney Abbott employees to manually download responsive files one-by-one, an activity that already will occupy significant amounts of Abbott employees' time—and significantly more if the start date extends back to 2018. Plaintiffs attempt to suggest that there is little burden to extending back to 2018 because "Abbott has indicated that it collected custodial documents going back to 2018 already." *Collecting* documents

generally is not the burdensome part of e-discovery: it is the review and production. Plaintiffs' date range proposal would dramatically expand the number of documents Abbott must review and produce with little expectation that those efforts would yield evidence probative of these cases.

Finally, Plaintiffs do not point to any compelling need to extend searches back to 2018. Plaintiffs' references to issues in 2010, 2018, and 2019 either concern non-microbiological issues, product that was ***never released***, reviews for which the FDA did not issue any regulatory observations or findings, and a single observation from 2019 about sampling for *Salmonella* testing that Abbott promptly addressed and that pre-dates the earliest filed *Salmonella* case by more than a year and a half. Plaintiffs' desire for a fishing expedition into earlier years finds no justification.

While Abbott maintains that a general start date of earlier than January 1, 2020 is not proportional to the needs of the case, Abbott has already produced, and is willing to agree to a compromise position that would include additional select categories of documents pre-dating 2020. For instance, to date, Abbott has produced all documents provided to FDA during its 2019 audit of the Sturgis facility and certain other documentation related to that audit (including the FDA's 483 and audit findings). And Abbott is willing to entertain other requests for documents from 2019, including certain sanitation and pest control records, batch records identified by Plaintiffs in Plaintiff Fact Sheets (to date, there are none), and test records associated with certain batches of product or time periods of production, to the extent proportional to the needs of the case. Abbott believes that the parties can work out targeted productions of certain non-custodial documents pre-dating January 2020 that allow Plaintiffs to obtain information relevant to their claims, while not imposing a disproportionate burden on Abbott.

ii. Casa Grande

PLAINTIFF'S POSITION:

In response to the PSC's Requests for Production, Abbott has maintained an objection to producing any documents that relate to facilities other than its Sturgis factory. To reach agreement, the PSC agreed to limit its requests returning documents about non-Sturgis facilities to only those within the United States that produce PIF. It is the PSC's understanding that there is only one non-Sturgis facility that meets this requirement—Abbott's Casa Grande facility.

The PSC has not yet received an answer from Abbott and therefore remains in the dark as to the defenses it intends to raise. However, there is a strong likelihood—if not certainty—that Abbott will claim that its Sturgis facility met then-existing industry standards and that any additional obligation would have been impracticable if not impossible. There is no convincing reason to deny the PSC the opportunity to learn what PIF production practices and standards were in place at Casa Grande to rebut such a defense. For example, Abbott should not be able to claim that certain microbial controls put in place at Casa Grande were not practicable for Sturgis.

This evidence may well provide the full context to gaining an understanding of how the conditions at Sturgis became, in the words of FDA Commissioner Califf, "shocking" and "egregiously unsanitary."[8] The factfinder may otherwise be left with a false impression that Sturgis' contamination problems were the result of a "few bad apples." Moreover, Abbott's experience producing PIF at Casa Grande informs, in part, Abbott's notice and knowledge about the need to control, if not eliminate, microbial contamination of PIF during its production. After all, Abbott's notice and knowledge involving *Cronobacter* contamination of PIF is not confined to within the Sturgis factory's walls. Finally, there is also the practical concern of how Abbott will

[8] Delauro.house.gov, https://delauro.house.gov/media-center/press-releases/delauro-statement-abbottfacility-reopening (last access on October 11, 2022).

handle the production of documents relating to the production of PIF, generally, or that relate to production of PIF at both facilities.

ABBOTT'S POSITION:

At the outset, Abbott does not believe this issue is yet ripe for the Court's attention and that the parties will still be able to reach a reasonable compromise on this issue.

Plaintiffs mischaracterize the position that Abbott has consistently expressed during the parties' discussions. Abbott has never asserted an objection "to producing any documents that relate to facilities other than its Sturgis factory." To the contrary, Abbott has produced, and will continue to produce, documents relating to other facilities ***where the documents also relate to Sturgis***. Abbott objects, however, to producing documents that relate ***only*** to other facilities.

The reason for Abbott's position is simple: the recall at issue *only* involved powdered infant formula from the Sturgis, Michigan plant and all of the cases in the MDL allege injuries resulting from product manufactured at Sturgis. This is not surprising considering the JPML's order establishing the MDL stated that "[a]ll actions can be expected to share factual questions arising from alleged contamination of certain powdered infant formulas manufactured at Abbott's manufacturing facility in Sturgis, Michigan." ECF 1, Aug. 2, 2022 Transfer Order, at 1. Expanding the bounds of relevance to encompass other factories, such as Casa Grande, heightens the risk that discovery in this case will become distracted by fishing expeditions into the practices and procedure of other factories decidedly not at issue in this MDL and risks significantly expanding the discovery burden.

Plaintiffs' only rationale for expanding the scope of relevance to embrace Casa Grande appears to be the *possibility* that Casa Grande *might* utilize different practices or procedures than Sturgis. They cannot point to anything concrete, nor do they allege even generally, that they are

aware of differences in procedure or practice between the two facilities. Such speculation is insufficient to justify this unnecessary expansion of the relevance boundaries, particularly here when both the recalled products and the plaintiffs' consumption of product only involve the Sturgis facility. "The discovery rules are not a ticket . . . to an unlimited, never-ending exploration of every conceivable matter that captures an attorney's interest." *Gross v. Chapman*, No. 19 C 2743, 2020 WL 4336062, at *4 (N.D. Ill. July 28, 2020).

iii. Preterm Infant Litigation Productions

PLAINTIFF'S POSITION:

The parties also discussed making available to the PSC certain documents produced in *In re: Abbott Laboratories, et al., Preterm Infant Nutrition Products Liability Litigation* MDL 3026, presided over by Chief Judge Rebecca R. Pallmeyer, currently pending in this District.

Both Johnson and Becker as well as Aylstock, Witkin, Kreis & Overholtz firms are heavily involved in the Preterm Infant Nutrition litigation that involves infant formula produced by Abbott and another manufacturer. While that litigation involves preterm infants less likely to have been fed PIF rather than ready-to-feed formulas, through the course of ongoing document review, counsel in both firms have come across documents that are unquestionably relevant and responsive to the PSC's requests for production in this matter. These documents are subject to a protective order in the Preterm Infant Nutrition litigation that would prevent dissemination to other counsel in this MDL that are not involved in that litigation.

The PSC has offered a simple, practical compromise. Specifically, the PSC asked Abbott to run the search terms agreed to in this litigation against the documents produced in the Preterm Infant Nutrition litigation, which have already been reviewed for privilege and work product. Counsel for Abbott in this litigation has been in contact with counsel for Abbott in the Preterm Infant Nutrition litigation and the PSC awaits a definitive commitment from Abbott to a process

making available these documents in this litigation. The inevitable alternative is a resource-intensive *ad hoc* process where only certain members of the PSC subject to the MDL 3026 Protective Order must petition the Court to review documents for responsiveness or relevance despite having hit on agreed-upon search terms.

ABBOTT'S POSITION:

Plaintiffs request that Abbott reproduce a large volume of documents from a separate MDL raising substantively distinct claims should be denied. The Preterm Infant Nutrition Litigation involves claims alleging that Abbott's preterm infant products have a design defect that caused preterm infants to suffer a gastrointestinal disease (necrotizing entercolitis). As Plaintiffs acknowledge, those claims do not involve powdered infant formula at all but instead relate primarily to ready-to-feed formulas (such as liquid formula) that are typically offered to preterm infants. The ready-to-feed liquid products at issue in the Preterm Infant Nutrition Litigation are not manufactured at Abbott's Sturgis facility and documents related to those other products have limited to no relevance to Plaintiffs' claims here related to powdered products manufactured at Sturgis. The Preterm Infant Nutrition claims do not involve any allegations of microbiological contamination, nor do they allege any connection between the gastrointestinal disease at issue there and manufacturing practices at Sturgis, which is not surprising considering the products and facilities at issue in the two MDLs are different. Moreover, none of the document custodians in the Preterm Infant Litigation are Sturgis employees and few, if any, are even in the Quality Assurance department of Abbott Nutrition. Notably, the Preterm Infant Litigation claims also center on a different time period: the relevant date range for document production goes as far back as the year 2000.

Given these substantial differences in the cases, Plaintiffs' "simple, practical compromise," as explained during the parties' discussions, that Abbott should run a single (very broad) search term across the entire production from a separate MDL necessarily would require Abbott to produce a very large volume of irrelevant documents. If Abbott were to accept Plaintiffs' proposal, it would require the production of ***327,567*** documents (more than 2 million pages)—which is ***more than half*** of all documents produced in the Preterm Infant Litigation. That number that will only continue to increase as Abbott makes additional productions in the Preterm Infant Litigation.

There is no need to run broad, untargeted terms with no date restrictions against a large volume of custodians who have zero (or, at most, minimal) touchpoints to powdered infant formula production at Sturgis. To the extent Plaintiffs are aware of custodians in the Preterm Infant Litigation that they believe have relevant knowledge or documents, they can request that Abbott add them as custodians in this MDL—something they already have done. (It bears noting that Abbott has already agreed to 29 custodians in this MDL, and Plaintiffs are seeking still more, which the parties are continuing to discuss.) Whether Abbott agrees will depend on the facts and circumstances particular to each proposed custodian, but that process is far more likely to lead to probative evidence than the blunt, untargeted process Plaintiffs propose here.

REPORT ON *WILLOUGHBY* ACTION

I. PLAINTIFFS' STATEMENT

Plaintiffs have served two sets of requests for the production of documents (non-duplicative of the documents requests in the MDL) and one set of interrogatories. Abbott has responded and objected to the first set of requests for production and answers to the interrogatories and responses to the second set of requests for production are, presumably, forthcoming. The parties have met and conferred regarding Abbott's responses and objections to the first set of

production requests. The parties were able to work through most of their issues and/or disagreements, with one exception.

The parties dispute the relevance of documents relating to marketing/advertising and labeling that do not specifically refer to heavy metals. In Plaintiffs' view, Abbott's marketing and/or labeling considerations and decisions beyond heavy metals are squarely relevant under Federal Rule of Civil Procedure 26. Such documents are directly relevant because they reflect Abbott's knowledge and decision-making processes relating to information it deems relevant or material to its marketing and/or labeling to consumers. For example, consumer surveys exploring what consumers view as important that may discuss safety or toxins would not be included if Abbott limits it searches to documents that mention heavy metals. Such documents would nonetheless be relevant to the claims in this case. In addition, because this case centers on omissions, a refusal to expand the searches beyond specific references to heavy metals would mean that there would be *no production* of any proposed or actual labels or marketing statement/s. Abbott's position also ignores Plaintiffs' claim relating to the overall impression of labels. The nondisclosure of heavy metals in combination with the information Abbott does include is misleading. Therefore, documents that address the background of statements relating to the nutritional and developmental benefits of the infant formula would, at the very least, be relevant as to why Abbott chose to include such information on its labels and Abbott's understanding of how consumers are likely to view such marketing statements. In preparation of this Joint Status Report, Abbott indicated that it intends to seek a Protective Order to limit its production in response to Plaintiffs' requests relating to these issues. In Plaintiffs' view, such relief would require the filing of a motion so that Plaintiffs may have a full opportunity to respond to Abbott and fully apprise the Court of their opposition.

With regard to document productions, although Abbott has produced over 240,000 pages of documents in the MDL action relating to recall of product manufactured or its Sturgis plant, Abbott has not produced any documents relating specifically to Willoughby. Abbott has agreed that the *Willoughby* Plaintiffs may have access to all documents produced in the MDL based on Abbott's view that at least some of those documents are relevant and responsive. Abbott has asked Plaintiffs to coordinate with Plaintiffs' MDL counsel to access that production. It is currently unclear whether *Willoughby* Plaintiffs' access through the MDL will work logistically; it may be simpler for Abbott to provide the load file to counsel for the *Willoughby* Plaintiffs directly. Plaintiffs will continue to work with Abbott and the MDL Plaintiffs to obtain access to those documents. Those documents aside, Abbott's discovery obligations to the *Willoughby* Plaintiffs remain.

Abbott has served Plaintiffs with sixty-eight requests for production and twenty numbered interrogatories. The parties have agreed on a response date and Plaintiffs will be responding as agreed.

The parties have also agreed to adopt the Protective Order and the ESI Protocol which the Court approved in the MDL.

II. ABBOTT'S STATEMENT

Case Status

Abbott has agreed that Plaintiffs may access any documents produced in the Recall MDL—some 250,000 pages to date—through the discovery platform operated by the MDL Plaintiffs.

On May 30, 2023, Plaintiffs served their First Set of RFPs on Abbott to supplement MDL discovery. Abbott timely served responses and objections. On July 13, 2023, the parties met and conferred. With one significant exception, addressed below, it appears that the parties have now reached agreement on an appropriate narrowing of these RFPs. Abbott is in the process of

collecting potentially responsive documents and intends to produce responsive documents on a rolling basis starting shortly.

On June 23, 2023, Abbott served its First Set of RFPs and First Set of Interrogatories on Plaintiffs. Plaintiffs requested a 30-day extension of their response date, which Abbott granted. Plaintiffs' responses to the RFPs and Interrogatories are now due on August 23, 2023.

On July 20, 2023, Plaintiffs served their First Set of Interrogatories on Abbott. Abbott is preparing its objections and responses, which are due on August 21, 2023.

On July 24, 2023, Plaintiffs served their Second Set of Document Requests on Abbott, seeking documents related to a lawsuit involving heavy metals that was filed in another jurisdiction. Abbott is preparing its objections and responses, which are due on August 23, 2023.

The parties have also agreed on a stipulated Order governing ESI issues that tracks the analogous Order entered in the Recall MDL. The parties intend to submit that Order to the Court shortly.

Discovery Dispute

The parties have reached an impasse regarding certain requests in Plaintiffs' First Set of RFPs. *See generally* Exhibit A (Abbott's Responses & Objections). The dispute concerns several RFPs related to the labeling, marketing, and advertising of the Similac products at issue (the "Products"), which go far beyond the bounds of this case:

> RFP No. 2: All DOCUMENTS and COMMUNICATIONS CONCERNING **the marketing, advertising, or LABELING of any of the PRODUCTS**…
>
> RFP No. 4: All DOCUMENTS and COMMUNICATIONS CONCERNING any actual and estimated increases in sales **due to the marketing, advertising, and LABELING of the PRODUCTS** including but not limited to internal projections, research, analyses, and sales data comparisons (e.g., year-over-year).

> RFP No. 5: All DOCUMENTS CONCERNING **marketing budgets, marketing plans, and COMMUNICATIONS between and among members of DEFENDANT'S marketing team relating to the PRODUCTS**.
>
> RFP No. 6: All DOCUMENTS and COMMUNICATIONS CONCERNING **any market research and/or analyses that form the basis of the marketing, advertising, and/or LABELING of the PRODUCTS**….
>
> RFP No. 7: All DOCUMENTS and COMMUNICATIONS CONCERNING DEFENDANT'S TARGET CUSTOMER(S) or TARGET MARKET(S), including but not limited to **how and whether the LABELS impact TARGET CUSTOMERS purchasing decisions**.
>
> RFP No. 8: All DOCUMENTS and COMMUNICATIONS to or from DEFENDANT relating to **whether the PRODUCTS' ingredients reflect the LABELS**…
>
> RFP No. 10: All DOCUMENTS CONCERNING **any research, surveys, TESTING, and/or analysis that support the marketing, advertising, and/or LABELING of the PRODUCTS**.

Abbott has agreed to search for and produce documents responsive to these RFPs to the extent they refer to heavy metals, or to any particular heavy metal (*e.g.*, lead)—but not otherwise.

On July 13, 2023, the parties conducted a meet-and-confer, during which Plaintiffs' counsel contested Abbott's proposed narrowing. *See* Exhibit B (Abbott's July 19, 2023 Letter). For example, Abbott asked whether Plaintiffs would insist that it produce a hypothetical email discussion among its marketing employees regarding whether to make a "non-GMO" (*i.e.*, no genetically modified organisms) claim, or a hypothetical scientific study performed to support a "non-GMO" claim. Plaintiffs answered yes: they seek literally *all* documents and communications with regard to *any* aspect of Similac's labeling, marketing, or advertising, including substantiating materials with regard to any Product claim Abbott has made. *Id.* at 5.

Plaintiffs' *only* claim in this case is that Abbott misled consumers by failing to disclose the alleged presence of heavy metals on the labels of the Products. Plaintiffs' liability theory does not involve Abbott's *non-label* advertising, marketing, or promotion (*e.g.*, television or social media),

none of which Plaintiffs allege they saw. Nor does Plaintiffs' liability theory involve any affirmative marketing claim, such as "non-GMO," "no artificial growth hormones," and the like. Plaintiffs have repeatedly confirmed this.[9] The Court explicitly relied on Plaintiffs' assurances in construing the scope of their claims,[10] and in dismissing those portions of Plaintiffs' complaint that went beyond omissions concerning heavy metals in the Products' labels. *See, e.g.*, ECF 51 at 20 ("Thus, any claims are dismissed to the extent they are based on alleged misrepresentations on Abbott's website.").

Abbott does not dispute—and, indeed, will stipulate—that it never mentioned heavy metals in the Products' labeling or advertising. Moreover, as Abbott has informed Plaintiffs, it will be producing within the Recall MDL the contents of its "Pepperflow" database, a historical repository of Abbott's approved labeling, advertising, and promotional materials for the Products. Plaintiffs need no additional discovery to confirm whether heavy metals were disclosed or what Abbott's labels actually said. To be clear, Abbott is not objecting to discovery to assess what Abbott knew about the Products' alleged heavy metal content; whether Abbott ever considered disclosing heavy metals; or whether Abbott conducted any research to gauge consumers' views on heavy metals. Abbott's proposed narrowing of Plaintiffs' RFPs would permit full exploration of these issues.

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[9] *See, e.g.*, Plaintiffs' Opp. to Abbott's Mot. to Dismiss (ECF 30) at 1 ("[This is] a case … exclusively alleging economic harm … based on the *uniform omissions* on Similac®'s infant formula packaging"), 4 ("Plaintiffs' class action claims involve … material omissions from Abbott's product packaging" concerning "the presence or risk of heavy metals"), 23-24 ("Plaintiffs' claims rest on the fact that they were unaware the Infant Formula contained … Heavy metals, and would not have purchased the Infant Formula if that information had been fully disclosed"), 31 ("Plaintiffs' allegations … are based not on misrepresentations but *omissions*.").

[10] *See, e.g.*, Order on Abbott's Mot. to Dismiss (ECF 51) at 1 ("[P]laintiffs … allege that the products contained heavy metals … which were not disclosed in the labeling."), 19 ("Willoughby clarifies in her response brief that she is only bringing claims based on alleged omissions, not misrepresentations."), 20 ("[I]n response to Abbott's contention that Willoughby does not allege that the statements identified in her complaint are false, Willoughby reaffirms that her claims 'are based on omissions.'"), *id.* ("Willoughby disavowed any claims arising from [Abbott's] website statements in response to Abbott's argument that … [no] plaintiff read the website before making their purchases.").

Plaintiffs' demand that Abbott review and produce *all* documents concerning *any* aspect of the Products' labeling, marketing, and promotion—including scientific substantiation—would go far beyond the scope of Plaintiffs' claims; impose an undue and disproportionate burden; and circumvent the Court's motion-to-dismiss order. Courts have repeatedly deemed such marketing "fishing expeditions" improper. *See, e.g.*, *Alcon Ent'mt, LLC v. Autos. Peugeot SA*, 2021 WL 8055689, at *2 (C.D. Cal. May 7, 2021) (rejecting, as a "classic 'fishing expedition,'" RFPs seeking discovery concerning "all Peugeot automotive advertising and promotion documents," including those "*not* connected to the promotion and campaign at issue in this case"); *Smith v. Blue Shield of Cal. Life & Health Ins. Co.*, 2016 WL 10599498, at *3-4 (C.D. Cal. Nov. 14, 2016) (quashing, as "not relevant," RFP seeking documents concerning all of Blue Shield's "marketing 'plans and tactics,'" including those "having nothing to do" with the prerecorded telephone message being challenged); *Alloc, Inc. v. Unilin Beheer B.V.*, 2006 WL 757871, at *5 (E.D. Wis. Mar. 24, 2006) (quashing, as "too broad," RFP seeking "all communications concerning the accused products" by or from Alloc's marketing personnel, and limiting request "to those documents relating" to "the claims at issue in this litigation").

Plaintiffs' justification for the breadth of these RFPs has been that "Abbott's decision-making processes and background as to what information it does use for marketing and labeling is relevant to understanding its decisions relating to Heavy Metals." Courts have properly rejected this reasoning. *See Smith*, 2016 WL 10599498, at *3-4 (rejecting argument that "*all* of Blue Shield's marketing plans and tactics are relevant to show the context in which the [challenged] Prerecorded Message was sent," and restricting discovery to the challenged telephone message). It is sheer speculation that conversations, studies, or analyses related to a "non-GMO" claim—to give just one example—would be "relevant to understanding [Abbott's] decisions relating to

Heavy Metals." And regardless, "relevance alone does not translate into automatic discoverability…. An assessment of proportionality is essential." *Motorola Sols., Inc. v. Hytera Commc'ns Corp.*, 365 F. Supp. 3d 916, 924 (N.D. Ill. 2019); Fed. R. Civ. P. 26(b)(1).

Plaintiffs now argue that, "because this case centers on omissions, a refusal to expand the searches" beyond heavy metals "would mean that there would be *no production* of any proposed or actual labels or marketing statements." *Supra* (emphasis Plaintiffs'). That is incorrect: again, Abbott's Pepperflow database, which will be produced, contains all historical labels and marketing materials approved for use, whether they mention heavy metals or not.

Plaintiffs also argue that "consumer surveys … that may discuss safety or toxins would not be included if Abbott limits its searches to documents that mention heavy metals." *Supra*. But Plaintiffs have demanded all documents relating to *any* aspect of Abbott's labeling or marketing, not just consumer surveys about "safety" or "toxins." And even such a narrowed request would still be overbroad, potentially requiring review and production of documents on subjects ranging from microbiological sterility (the subject of the dismissed "sanitation theory" claims), to whether cow's-milk proteins in Abbott's formulas allegedly cause necrotizing enterocolitis (the subject of an ongoing MDL before Judge Pallmeyer, No. 22-cv-0071), to pesticide residues or allergens.

Abbott has already made significant concessions to Plaintiffs with respect to their RFPs. For instance, even though Plaintiffs' claims concern only *product labeling*, Abbott has also agreed to review and produce documents that bear on non-label advertising and promotion, to the extent those documents may mention heavy metals. Abbott has agreed to collect and produce standard operating procedures regarding the formulation and manufacture of the Products—even those that have nothing to do with heavy metals. Finally, Plaintiffs also have access to voluminous discovery from the Recall MDL that goes well beyond the issue of heavy metals.

Where Plaintiffs have explicitly limited this case to the *omission* of information about *heavy metals* from the products' *labels*, Abbott's proposed narrowing of the RFPs above to documents that actually concern heavy metals is reasonable and proportionate.

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CERTIFICATE OF SERVICE

I hereby certify that on August 4, 2023, a copy of the foregoing document was filed electronically. Notice of this filing will be sent to counsel of record by operation of the Court's electronic filing system. Parties may access this filing through the Court's system and/or by e-mail.

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